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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/882,431 06/25/97 ULRICH R 003/037/SAP

HM22/0922  
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EXAMINER

ALLEN, M

ART UNIT

PAPER NUMBER

1631

21

DATE MAILED:

09/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

08/882,431

Applicant(s)

Ulrich et al.

Examiner

Marianne P. Allen

Group Art Unit

1631



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-70 and 100-109 is/are pending in the application

Of the above, claim(s) 2, 3, 7-11, 15-17, 19, 20, 24-28, 32-36, 40-42, 45, 46, 50- is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 4-6, 12-14, 18, 21-23, 29-31, 37-39, 43, 44, 47-49, 53, 56-58, 62, and 65-67 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-70 and 100-109 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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The request filed on 5/5/00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/882,431 is acceptable and a CPA has been established. An action on the CPA follows.

The petition to revive abandoned application 08/882,431 for purposes of continuity with the CPA was granted on 7/10/00 (Paper No. 19).

Claims 2-3, 7-11, 15-17, 19-20, 24-28, 32-36, 40-42, 45-46, 50-52, 54-55, 59-61, 63-64, 68-70, and 100-109 remain withdrawn from further consideration by the examiner as being drawn to a non-elected invention.

Applicant is again advised that generic claims 1, 18, 43-44, 53, and 62 have been examined on the merits only to the degree that they reflect the elected invention Staphylococcal enterotoxin B and should be amended to reflect the elected invention. Applicant is further advised that if they fail to do so, at least a double patenting rejection over the claims in co-pending application 09/144,776 (directed to SEA superantigens) as well as the art rejections in the co-pending application will be made herein.

Applicant is reminded that this application contains claims drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the previous final rejection should have included cancelation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01. Applicant was also reminded of this in the Advisory Action (Paper No. 14).

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The amendment filed 5/5/00 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The information regarding pETB2360210P appears to be new matter. Note that claim 37 recites a different construct, pETB2360210. Clarification is requested.

Applicant is required to cancel the new matter in the reply to this Office action.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. Correction of the following is required: The recombinant DNA construct pETB899445C recited in claim 39 does not appear to be disclosed in the specification. Previous Office actions erroneously referred to pETA489270C which is recited in claim 36, a non-elected claim.

Applicant is reminded that the rejection of claims 1, 18, 43-44, 53, and 62 under 35 U.S.C. 102(b) as being anticipated by Hayball et al. (International Immunology, 1994) was withdrawn in view of applicant's amendment to the claims. However, in view of the new matter rejection, this art could be reapplied once the new matter rejection is resolved.

Claims 1, 4-6, 12-14, 18, 21-23, 29-31, 37-39, 43-44, 47-49, 53, 56-58, 62, and 65-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 has been amended to refer to multiple subsets of T cells with basis given as Examples 4, 8, and 9. Those examples referring to particular constructs of SEA are not germane as the elected species is SEB. Furthermore, particular constructs with these properties cannot be viewed as basis to support a generic claim to any superantigen toxin encompassed by the claims. It is unclear if any of the exemplified and particularly claimed SEB mutants exhibit this property. Clarification is requested with respect to the particularly claimed SEB mutants. A fair reading of the specification would not convey to one of ordinary skill in the art that either a generic class of superantigen vaccines with these particular properties or a generic subclass with respect to SEB vaccines were contemplated as the invention. Applicant is again requested to point to particular basis in the specification by page and line number to support this generic concept.

Applicant's arguments are confusing enablement with written description. A new matter rejection is a written description rejection and addresses whether the invention as claimed is described or contemplated in the specification as filed.

In addition, the enablement of claim 38 requires availability of the named DNA constructs and a deposit should have been made in accordance with MPEP 2402 as set forth in the prior Office action. In order to certify that the deposit meets the criteria set forth in MPEP 2402, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement

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by an attorney of record over his or her signature and registration number. Applicant is advised that the Patent Office accepts Budapest approved deposits, as long as assurance is provided that the deposited materials will be made irrevocably available with no restrictions upon issuance of a patent. No such statement has been provided nor does the specification appear to reflect the deposit information (ATCC numbers, date of deposit, address of the depository, etc.).

The deposit of plasmids according to the Budapest Treaty is noted on page 7 of the response filed 12/16/99 (Paper No. 13). However, upon further review, the deposit for claim 38 is not mentioned.

Claims 12-14, 29-31, 47-49, 55-58, and 65-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12-14 and 29-31 are directed to DNA fragments which encode whereas the claims upon which they depend (4-6 and 21-23) are directed to particular DNA fragments. As such, these claims may not be properly dependent in that they fail to include all of the limitations of the claims upon which they depend (i.e. they are broader than the claims upon which they depend as they encompass degenerate sequences). Alternatively, these claims could be merely confusing in that they are intended to be directed to only the portion of the sequence that encodes. For example, claim 4 is directed to SEQ ID NO: 5 and claim 12 which depends upon it is directed to sequences encoding SEQ ID NO: 6. Either claim 12 is improperly dependent or is confusing in

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that it is intended to be only that portion of SEQ ID NO: 5 that encodes SEQ ID NO: 6.

Clarification is requested.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 9:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028. Official FAX communications may be directed to either (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Marianne P. Allen*  
MARIANNE P. ALLEN  
PRIMARY EXAMINER  
~~GROUP 1800~~  
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